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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,388	06/28/2002	Yoav Blatt	6727/OK322USO	3273

7590 03/31/2004

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,388	BLATT ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/08/02.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 3/24/04
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 11/08/02, and Filing Receipt Status Request filed 10/21/02.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2 and 21-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Thurn et al. US 6,004,558.

Thurn discloses an oral composition comprising extract of isoflavone-containing plants, such as soy or clover (column 2, lines 53-67, and column 3, lines 25 through column 4, lines 1-8). The oral composition is in the form of capsule, tablet, cachet, powder or granule, further comprises carrier, such as diluent, dispersing agent, lubricant, binder, and the like (column 4, lines 35-64). Thurn further teaches enteric

coating (controlled release) comprises cellulose polymer, including acetyl-cellulose phthalate and hydroxypropylmethylcellulose phthalate (column 5, lines 10-20). The amount of isoflavone in the dosage form is from 0.5-59% (column 4, lines 9-22).

It is noted that Thurn does not teach the storage stability for at least six months. However, it is the examiner's position that the composition taught by Thurn would exhibit the same storage stability because Thurn recognizes the desire of obtaining a stable composition in the use of stabilizer (column 5, lines 28-30). When the claimed and prior art products are identical or substantially identical in structure or composition, the properties being claimed is inherent. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurn et al. US 6,004,558, in view of Blatt et al. US 6,340,478.

Thurn is relied upon for the reason stated above. Thurn teaches controlled/sustained release composition using enteric coating polymer, including acetyl-cellulose phthalate and hydroxypropylmethylcellulose phthalate (column 5, lines 10-20). Thurn does not teach the release profile as claimed in claims 3, 11 and 15.

Blatt teaches an oral composition for controlled release or stable storage of granulated herbal extract from herbal plants or portions of herbal plants (see abstract, and column 1, lines 45-51). The composition is in the form of tablet or capsule comprising coated granulated herb and at least one carrier for controlled release and zero linear release (column 1, lines 53-64, and column 3, lines 8-20). The granulated herb is coated with enteric coating polymer including, ethyl cellulose, hydroxypropylmethyl cellulose, or combination thereof having weight ratio from about 0.05 to about 0.40 (columns 3-4). Thus, it would have been obvious for one of ordinary skill in the art to modify the plant extract composition of Thurn using the controlled release plant extract composition in view of the teaching of Blatt with the expectation of providing a controlled release dosage form of isoflavone-containing plant extract useful in pharmaceutical art.

Claims 1-17 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blatt et al. US 6,340,478, in view of Bucci US 6,117,429.

Blatt is relied upon for the reason stated above. Blatt teaches extract of herb or plant, but is silent as to the teaching of isoflavone.

Bucci teaches an oral composition comprising natural product, such as isoflavones and similar flavonoid compounds from herbs or plants, powder thereof, semi-purified and purified extract thereof (column 3, lines 39-51, and column 5, lines 1-27). The oral composition is in the form or tablet, capsule, with carrier and excipient to mast the unpleasant tastes (column 8, lines 57 through column 9, lines 1-26). Thus, it

would have been obvious for one of ordinary skill in the art to modify the controlled release composition of Blatt using the natural product of plant or herb extract composition in view of the teaching of Bucci with the expectation of providing a controlled release dosage form containing isoflavone useful in pharmaceutical art.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blatt et al. US 6,340,478 and Bucci US 6,117,429, in view of Shlyankevich US 5,424,331.

Blatt and Bucci are relied upon for the reason stated above. The references are silent as to the teaching of the claimed active agents.

Shlyankevich teaches a pharmaceutical composition comprising isoflavone includes daidzein, genistein, glycitein, and their glycosides, such as daidzin, genistin, and glycitin (column 4, lines 52-59). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify the isoflavone extract of Blatt and Bucci using the isoflavones in view of the teaching of Shlyankevich with the expectation of providing a controlled release dosage form comprising well known isoflavone, such as daidzein, genistein, glycitein, and their glycosides.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barnes et al., Kanaoka et al, Gana-Calvo, Hite et al., and Akata are cited as of interest for the teachings of isoflavone composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600